NIH Update

Federal Demonstration Partnership
May 11, 2017

Michelle G. Bulls, Director
Office of Policy for Extramural Research Administration,
OER, NIH

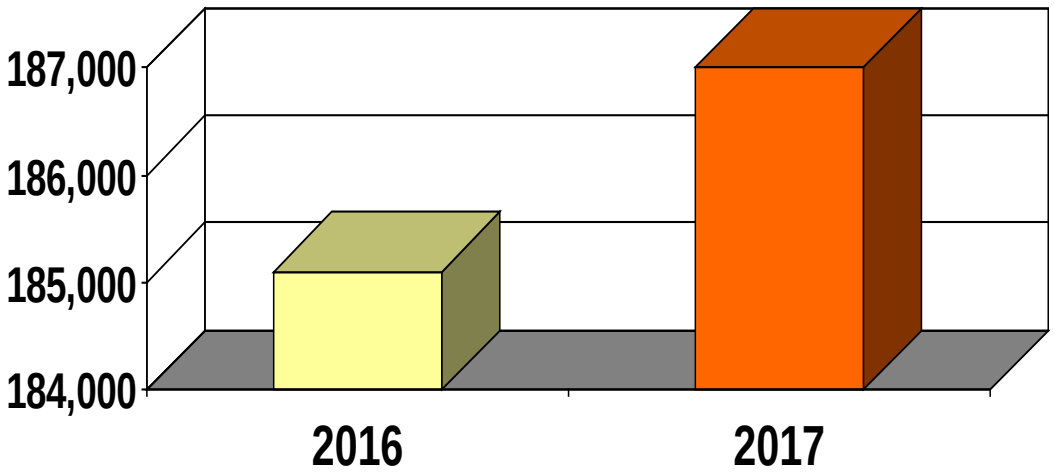
National Institutes of Health
Office of Extramural Research

NIH FY 2017 Appropriation Breaking Information

- NIH is funded under HR 244, the Consolidated Appropriations Act, 2017 signed by the President on May 5, 2017 that will fund the government through September 30, 2017.
- NIH funded at approximately $34.7 Billion, exclusive of funding provided through the 21st Century Cures Act.
- Increase of approximately $3 Billion over FY16.
- Watch for further details.

NIH FY 2017 Salary Cap

Limited to Executive Level II – increased from $185,100 to $187,000, effective as of January 08, 2017.



See NOT-OD-17-049 for additional information

21st Century Cures Act

Landmark piece of legislation - accelerating the discovery, development and delivery of 21st century cures and other purposes.

- Reducing Administration Burden for Researchers
  - Sub-recipient monitoring
  - FCOI
  - Financial Expenditure Reporting
  - Documentation of Personnel Expenses
  - Animal Care and Use in Research
  - Research Policy Board

https://www.congress.gov/bill/114th-congress/house-bill/34

Automated Post Award Changes

Effective March 2, 2017, recipients of NIH awards can submit the following prior approval requests electronically through eRA Commons.

Prior Approval Request for Change of PD/PI

- SOs can initiate the request for a Change of Program Director/Principal Investigator (PD/PI) electronically through eRA Commons via Prior Approval.

Prior Approval Request for No Cost Extension (NCE)

- SOs will be able to request NCEs (in addition to the requests made under expanded authority) electronically through eRA Commons via Prior Approval.

For additional details please see eRA Commons Online Help

Adjustment to NRSA Postdoctoral Stipends

As acknowledged within NOT-OD-17-002, effective December 1, 2016 recipients of NRSA institutional training grants and individual fellowship awards supporting currently active postdoctoral trainees or fellows with 0-2 years of experience may request supplemental funding to increased stipends.

In order to accurately document the stipend level increase in xTrain. Recipients will need to follow the procedures outlined in NOT-OD-17-057.

Applications must be submitted by **June 30th, 2017**.

Reporting Preprints and Other Interim Research Products

NIH encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work.

Therefore, NIH will allow investigators to cite their interim research products anywhere other research products are cited. These sections include the following:

- R&R Other Project Information Form, Bibliography & References Cited
- R&R Senior/Key Person Profile (Expanded) Form, Biographical Sketch
- PHS 398 Research Plan, Progress Report Publication List
- PHS 398 Career Development Award Supplemental Form, Progress Report Publication List
- PHS Fellowship Supplemental Form, Progress Report Publication List
- RPPR, section C - Products

Effective date:

- Applications submitted for the May 25, 2017 due date and thereafter
- RPPRs submitted on or after May 25, 2017

See NOT-OD-17-050 for details.

NIH Implementation of the Research Terms and Conditions (RTCs)

Effective April 3rd, 2017, the Research Terms and Conditions apply to all NIH grants and cooperative agreements with the exceptions noted in the NIH Agency Specific Requirements.

Additional supporting documents included as part of NIH's implementation of the RTCs:

- Appendix A, Prior Approval Matrix
- Appendix B, Subaward Requirements Matrix
- Appendix C, National Policy Requirements Matrix

NIH implementation of these Federal-wide Research Terms has no significant change in the requirements or terms and conditions for NIH awardees.

Reminder of the types of NIH RPPRs

NIH now offers three types of RPPRs, each one is outlined in the NIH RPPR Instruction Guide.

1. **Annual RPPR** – Use to describe a grant's scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year.

2. **Final RPPR** – Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.

3. **Interim RPPR** – Use when submitting a renewal (Type 2) application. If the Type 2 is not funded, the Interim RPPR will serve as the Final RPPR for the project. If the Type 2 is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.

Stay tuned for the release of additional resources such as webcast and FAQs related to NIH's implementation of the Final-RPPR and Interim-RPPR!!

See NOT-OD-17-022 and NOT-OD-17-037

Reminder of NIH Policies Enhancing Clinical Trial Stewardship & Transparency

NIH announced the following policies to improve its stewardship of clinical trials:

- Expects all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials be trained in Good Clinical Practice (GCP). – Effective as of January 1, 2017

- Expects all NIH-funded clinical trials are registered and that results are submitted to ClinicalTrials.gov whether or not subject to FDAAA. – Applies to grants, cooperative agreements, contracts, and intramural clinical trials submitted on or after January 18, 2017.

- Expects that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. – Applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after September 25, 2017.

- Requires that all applications involving one or more clinical trials be submitted in response to a clinical trial-specific FOA. – Effective for receipt dates on or after January 25, 2018.

See NOT-OD-17-043; NOT-OD-16-148; NOT-OD-16-149; NOT-OD-16-094 for additional information.

Check the Guide

For information on NIH grant policies, guidelines and funding opportunities, check the NIH Guide!

QUESTIONS ?